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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,182	11/26/2001	Jan Matthijs Jetten	BO 42503	9536

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EXAMINER
MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
1621	

DATE MAILED: 06/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/914,182	JETTEN ET AL.	
	Examin r	Art Unit	
	Traviss C McIntosh	1621	

-- The MAILING DATE of this communication appears on the cover sh t with the corresp nd nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. EPO 99200536.3, filed on 2/24/1999. However, the priority document number 99200536.3 does not claim the subject matter of claim 30 and the feature of "glyconic acid" of claim 28. Therefore, the priority document is not considered valid for claim 28 in part and claim 30 of the instant invention and the priority date for these will be 2/24/2000 based on PCT/NL00/00117.

Information Disclosure Statement

Acknowledgement is made of the Information Disclosure Statement submitted and will be taken into consideration only in light of the portion which was submitted in English.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-23, 25-28, and 31-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 6-10 of copending Application No. 09/913,596 ('596). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the application and copending application ('596) are drawn to a process for oxidizing a primary alcohol function of a carbohydrate using a nitroxyl compound (TEMPO) in the presence of enzymes, oxidizing agents, and metal complexes. The enzymes of reference in both applications include peroxidase, polyphenol oxidase, and laccase. Further, the instant application and ('596) are both drawn to an oxidized carbohydrate containing at least 1 cyclic monosaccharide chain group carrying a carbaldehyde group per 100 monosaccharide units per average molecule and additionally containing carboxyl groups. Both the instant and ('596) further claim a carbohydrate derivative in which at least part of the carbaldehyde groups introduced by oxidation have been converted to a group with the formula –CH=N-R or $-CH_2$-NHR, wherein R is hydrogen, hydroxyl, amino, or a group R^1, or OR^1 or NHR^1, in which R^1 is C_1-C_{20} alkyl, C_1-C_{20} acyl, a carbohydrate residue, or a group coupled with or capable of coupling with a carbohydrate residue. Additionally, both applications claim a carbohydrate derivative in which at least part of the carbaldehyde group has been converted to a group with the formula $-CH(OR^3)$-O-CH_2-$COOR^2$ or $-CH(-O-CH_2-COOR^2)_2$, in which R^2 is hydrogen, a metal cation or an optionally substituted ammonium group, and R^3 is H or a direct bond to the oxygen atom of a dehydrogenated hydroxyl group of the carbohydrate.

The examiner notes that the copending application ('596) is directed to cellulose and does not refer to oxidizing primary alcohols in the claims. It is known in the art and dictated in the specification that the primary alcohol function of the cellulose is what is actually being oxidized to the corresponding aldehyde and, if desired, to the carboxylic acid. It is further known that cellulose is a carbohydrate containing primary alcohol functions.

It would be obvious to one of ordinary skill in the art that the oxidation process and compounds claimed in the copending application ('596) and the instant application are substantially overlapping. The process and compounds of the instant invention must contain new and distinguishable measures over the previously filed copending application to be patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors include, but are not limited to:

1. The breadth of the claims,
2. The nature of the invention,
3. The state of the prior art,
4. The level of one of ordinary skill,
5. The level of predictability in the art,
6. The amount of direction provided by the inventor,
7. The existence of working examples, and
8. The quantity of experimentation needed to make and/or use the invention based on the content of the disclosure.

Claim 19 is drawn to a process for oxidizing primary alcohols using a nitroxyl compound and an oxidizing agent characterized in that the primary alcohol is in an aqueous medium comprising an enzyme capable of oxidation and/or a metal complex. Claim 24 is drawn to oxidizing a primary alcohol in the presence of a metal complex and wherein the enzyme is a hydrolase, preferably phytase or lipase.

The nature of the invention requires a close look at that which is provided in the claims and the scope of the content encompassed by the claim language. It is known in the art that primary alcohols are contained in carbohydrates. Enzymes are known to effect the rate at which a reaction will occur, for example, our bodies oxidize glucose within seconds in the presence of oxygen due to the enzymes in our bodies, however a glucose solution exposed to oxygen under

sterile conditions would show no appreciable change for months. It is known in the art that hydrolases catalyze hydrolysis reactions.

One of ordinary skill in the art would find it reasonable to predict that reactions involving enzymes and primary alcohols would have extremely diverse outcomes based on the precise products used. One skilled in the art would be aware of the fact that enzymes are extremely specific in their catalytic activity and that primary alcohols occur in a many number of different molecules. Due to the tremendous number of enzymes and compounds containing primary alcohols, one would have great difficulty in practicing the claimed invention without more guidance from the specification.

The instant application provides working examples showing oxidation reactions in the presence of a nitroxyl radical and oxidizing agent comprising: 1) laccase and pullulan, 2) peroxidase and starch, 3) laccase and starch, and 4) manganese and pullulan. There are no working examples which support the process of claim 24. The disclosure states that the claimed process can be used in alternative situations, however there is a lack of working examples to show the inventive step is functionally active and the broadly claimed subject matter is absolutely accurate. The mere mention of alternative situations without guidance is seen to be an invitation to experiment.

The instant specification is not seen to provide adequate guidance nor examples which would allow the skilled artisan to extrapolate from the disclosure and examples provided to enable the oxidation process of all primary alcohols in the presence of an enzyme capable of oxidation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 22, 24, 26, and 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 20 recites the broad recitation where "the nitroxyl compound is a di-tert-nitroxyl compound", and the claim also recites "especially 2,2,6,6-tetramethylpiperidin-1-oxyl", which is the narrower statement of the range/limitation. Claim 22 recites the broad limitation where the "enzyme is a peroxidase", and the claim also recites "especially horse radish, soy-bean, lignin peroxidase, or myelo- or lacto-peroxidase", which is

the narrower statement of the range/limitation. Claim 24 recites the broad limitation "where the enzyme is a hydrolase", and the claim also recites "especially phytase or lipase", which is the narrower statement of the range/limitation. Claim 31 recites the broad limitation "an oxidized carbohydrate", and the claim also recites "being selected from disaccharides, oligosaccharides, and polysaccharides of the glucan, mannan, galactan, fructan, and chitin types", which is the narrower statement of the range/limitation.

Claims 26 and 31 claim an oxidized carbohydrate or a derivative thereof. In the absence of the identity of moieties intended to modify an art recognized chemical core, described structurally or by chemical name, the identity of a derivative would be difficult to ascertain. In the absence of said moieties, the claims containing the term "derivative" are not described particularly sufficiently to distinctly point out that which applicant intends as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 30 is rejected under 35 U.S.C. 102(a) as being anticipated by Viikari et al. (WO 99/23117). The claim is directed to an oxidation process wherein the primary alcohol is comprised in a textile fiber, and as earlier noted, the priority document does not contain any reference to textile fibers, therefore the priority date of this claim is 2/24/2000.

Viikari et al disclose a process for oxidizing a primary alcohol in the presence of an enzyme and nitroxyl compound wherein the primary alcohol is in cellulosic textile fibers (abstract and page 5, lines 8-10). This disclosure in Viikari et al. anticipates claim 30.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over copending application number 09/913,596 ('596).

The claims of the instant invention are drawn to a process for oxidizing a primary alcohol, wherein the primary alcohol function is comprised in a carbohydrate, a steroid or in textile fibers. The oxidation process occurs in an aqueous medium in the presence of a nitroxyl compound (TEMPO) and either an enzyme or a metal complex. The enzyme can be an

oxidoreductase, peroxidase, polyphenol oxidase, laccase, or a hydrolase. Further, the claims of the instant invention are drawn to a carbohydrate derivative in which at least part of the carbaldehyde groups introduced by oxidation have been converted to a group with the formula –CH=N-R or $-CH_2$-NHR, wherein R is hydrogen, hydroxyl, amino, or a group R^1, or OR^1 or NHR^1, in which R^1 is C_1-C_{20} alkyl, C_1-C_{20} acyl, a carbohydrate residue, or a group coupled with or capable of coupling with a carbohydrate residue. Additionally claimed is a carbohydrate derivative in which at least part of the carbaldehyde group has been converted to a group with the formula $-CH(OR^3)$-O-CH_2-$COOR^2$ or $-CH(-O-CH_2-COOR^2)_2$, in which R^2 is hydrogen, a metal cation or an optionally substituted ammonium group, and R^3 is H or a direct bond to the oxygen atom of a dehydrogenated hydroxyl group of the carbohydrate.

'596 claims a process for oxidizing cellulose using a nitroxyl compound (TEMPO) and oxidizing agent in the presence of an oxidative enzyme or a metal complex and the enzyme being a peroxidase, polyphenol oxidase, or laccase. Further claimed is an oxidized cellulose derivative in which at least part of the carbaldehyde groups introduced by oxidation have been converted to a group with the formula –CH=N-R or $-CH_2$-NHR, wherein R is hydrogen, hydroxyl, amino, or a group R^1, or OR^1 or NHR^1, in which R^1 is C_1-C_{20} alkyl, C_1-C_{20} acyl, a carbohydrate residue, or a group coupled with or capable of coupling with a carbohydrate residue.

'596 does not specifically address a process for oxidizing the primary alcohol function where the primary alcohol is in a carbohydrate or steroid.

It would have been obvious of one of ordinary skill in the art at the time of the invention to include the statement of oxidizing primary alcohols comprised in carbohydrates and steroids since cellulose is a carbohydrate comprising a primary alcohol and a steroid is a lipid comprising

a primary alcohol function. The prior art of record provides sufficient motivation to oxidize a carbohydrate or steroid due to the fact that it is the primary alcohol function being oxidized in all instances.

Conclusion

Claims 19-36 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Traviss McIntosh
May 30, 2002

James Wilson
Primary Examiner
Group 1600